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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
(21 CFR 807.92) [21 CFR 807.87(H)]

CAP™ GREAT TOE RESURFACING HEMI-ARTHROPLASTY IMPLANT

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.87(h), this information serves as a Summary of Safety and Effectiveness for the CAP™ Great Toe Resurfacing Hemi-arthroplasty implant.

Submitted By:	STD Manufacturing, Inc. 1063 Turnpike Street Stoughton, MA 02072 (781) 828-4400
Date:	May 30, 2003
Contact Person:	Steven W. Ek, VP of Development
Proprietary Name:	CAP™ Great Toe Resurfacing Hemi-arthroplasty implant
Common Name:	Toe joint, Phalangeal (hemi-toe) prosthesis
Classification Name:	Toe joint phalangeal (hemi-toe) prosthesis
Device Classification:	Class II
Review Panel:	Orthopedic
C.F.R. identification reference:	21 CFR § 888.3730 (2002)
Product Code:	KWD
Indications for Use:	Hemi arthroplasty implant for first metatarsophalangeal joint for use in the treatment of patients with degenerative and post-traumatic arthritis in the first metatarsal joint in the presence of good bone stock along with the following clinical conditions; hallux valgus or hallux limitus, hallux

rigidus, and an unstable or painful metatarsal/phalangeal (MTP) joint. The device is a single use implant intended to be used with bone cement.

Substantial Equivalence Information:

The intended use, materials, and application of the Proposed device are substantially equivalent to those of the predicate devices. In determining substantial equivalence, STD Manufacturing's device, CAP™ Great Toe Resurfacing Hemi-arthroplasty implant, has been compared with the following legally marketed device to which the submitter claims equivalence.

- Implant, H.P. condylar, Dow Corning Wright (K781870)
- Swanson Titanium Great Toe Implant, Dow Corning Wright (K864492)
- K2 Hemi-Toe Implant System, Kinetikos Medical, Inc. (K023770)
- Futura Biomedical Metal Hemi Toe Implant, Futura Biomedical (K971047)
- Townley Great Toe Joint, Biopro, Inc. (K911378)

Device Description and Implantation Summary

The CAP™ Great Toe Resurfacing Hemi-arthroplasty implant is a cobalt chrome alloy, 2-piece implant to supplement first metatarsal phalangeal joint arthroplasty. The implant is designed to provide a smooth surface for the first metatarsophalangeal joint as a the treatment of patients with degenerative and post-traumatic arthritis in the first metatarsal joint in the presence of good bone stock along with the following clinical conditions; hallux valgus or hallux limitus, hallux rigidus, and an unstable or painful metatarsal/phalangeal (MTP) joint. The device is a single use implant intended to be used with bone cement.

The CAP™ Great Toe Resurfacing Hemi-arthroplasty implant consists of two components, a taper post component and an articular component, that mate together via a taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/prosthetic interface.

The first implant component is a Taper Post manufactured of a Ti-6Al-4V ELI alloy per ASTM F136. The Taper Post has a tapering distal tip, a full-length cannulation, and a proximal female taper bore.

The second implant is an articular component manufactured of a Cobalt-Chromium-Molybdenum alloy per ASTM F799 and ASTM F1537. The articular component has a bone contact surface that is coated with a CP Titanium coating

and a polished articular bearing surface. For greater detail, refer to section 8.2 to view engineering drawings illustrating the various components.

Utilizing the drill guide provided within the CAP™ Great Toe Resurfacing Hemi-arthroplasty implant instrumentation set, a surgeon is able to define a working axis that is normal to the articular cartilage surface at the site of the defect. After drilling a pilot hole, the Taper Post is screwed into place using the trial cap to ensure that the surface of the articular component will be tangent and congruent to the existing cartilage surface when seated. Using the contact probe instrument corresponding to the implant diameter, offset measurements are taken to define the topography of the patients surrounding articular surface by revolving the probe around a centering shaft coaxial to the working axis of the Taper Post. With these offset measurements, the surgeon is able to select the articular component (sized to match great toe metatarsal head) that will allow it to seat flush to the surrounding articular surface. Offset increments in .5mm sizes will allow for an optimal fit to the existing articular surface.

A reamer, which matches the articular component internal geometry is used to prepare the site for the prosthetic to be implanted. This allows for a precise fit of the implant to the prepared site and minimizes bone resection, so as to provide minimal impact to any future arthroplasty procedure. The articular component is then impacted to seat the taper interlock between the two components.

The prosthetic is intended to provide an effective means for treatment of patients with degenerative and post-traumatic arthritis, hallux valgus, hallux rigidus, hallux limitus, and/or an unstable or painful metatarsal/phalangeal (MTP) joint.

The device has been designed to offer a number of clinical benefits to the user and patient. The device is technically easy to implant, and offers the surgeon a high degree of precision and flexibility in sizing and fitting the articular component to the existing anatomy. A reduction in bone and articular cartilage resection is also offered over the predicate devices, providing a more physiologically normal joint in terms of load and impact distribution.

Non-clinical Testing conducted to determine substantial equivalence with the predicate devices

Mechanical test protocol has been completed using the proposed device including testing of the taper post component and the articular component per the guidelines established in CDRH Guidance Document for Testing Non-Articulating, Mechanically Locked, Modular Implant Components and ASTM F 1814 "Standard Guide for Evaluating Modular Hip and Knee Joint Components".

The following non-clinical tests were conducted to assess the device performance:

- Axial Assembly and Disassembly
- Rigidity Characterization
- Cyclic Fatigue Failure, Disassembly
- Fretting, Fretting/ Corrosion (ASTM F897)
- Resistance to Torque of Head Fixation" (ISO 7206-9)

Final results from these tests demonstrate that the devices meet established acceptance criteria in accordance with the identified industry standards.

Testing to document the required information for the vacuum plasma spray applied surface coating has been previously performed per guidelines established in CDRH Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Cement. This documentation exists in the Bio-Coat Master Device File MAF-1085 of which Arthrosurface has been given authorization to reference in support of this 510(k) submission.

CAP™ Great Toe Resurfacing Hemi-arthroplasty Implant

Substantial Equivalence Comparative Summary: Proposed Device and Predicate Devices

Product Name	Proposed Device: CAP™ Great Toe Resurfacing Hemi-arthroplasty implant	Predicate Device 1: H.P. Condylar Implant	Predicate Device 2: Swanson Titanium Great Toe Implant	Predicate Device 3: K2 Hemi-Toe Implant System	Predicate Device 4: Metal Hemi Toe Implant	Predicate Device 5: Townley Great Toe Implant
Manufacturer	Arthrosurface	Dow Corning Wright	Dow Corning Wright	Kinetikos Medical, Inc.	Futura Biomedical	Biopro, Inc.
K Number	TBD	K781870	K864492	K023770	K971047	K911378
Material:	Articular surface- Cobalt Chrome Alloy Bone contacting surface- Titanium	Articular Surface- Silicone Bone contacting surface - Silicone	Articular Surface- Cobalt Chrome Alloy or Titanium Bone contacting surface - Titanium	Articular Surface- Cobalt Chrome Bone contacting surface - Titanium	Articular Surface- Cobalt Chrome Bone contacting surface - Cobalt Chrome	Articular Surface- Cobalt Chrome Bone contacting surface - Cobalt Chrome
Mechanical Fixation	Taper Post installed as central post. Prosthesis mates into Taper Post via taper interlock.	Press fit	Press fit, no cement	Press fit, no cement	Press fit – for grit blasted Bone Cement – for Titanium plasma spray	Press fit no bone cement
Coating	Titanium plasma Coating	No coating	Unknown	titanium plasma coating	grit blasted / titanium plasma coating	Unknown
Single Stemmed	Yes	No- Double	Yes	Yes	Yes	Yes
Site Preparation	Resection of articular surface and bone	Resection of articular surface and bone	Resection of articular surface and bone	Resection of articular surface and bone	Resection of articular surface and bone	Resection of articular surface and bone

----- End of 510(K) Summary of Safety and Effectiveness -----



FEB 18 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Steven Ek
Chief Operating Officer
Arthrosurface, Inc.
378 Page Street, Unit 6
Stoughton, MA 02072

Re: K031859
Trade/Device Name: CAP™ Great Toe Resurfacing Hemi-arthroplasty
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: II
Product Code: KWD
Dated: November 18, 2003
Received: November 20, 2003

Dear Mr. Ek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

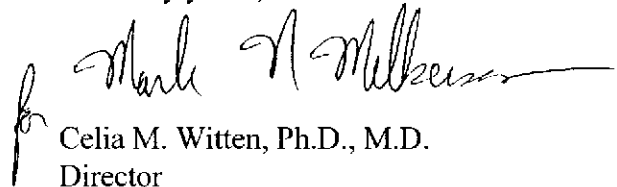
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Steven Ek

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over a horizontal line. To the left of the signature is a small, stylized initial or mark.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K031859

Device Name: **CAP™ Great Toe Resurfacing Hemi-arthroplasty**

Indications for Use:

Hemi-arthroplasty implant for first metatarsophalangeal joint for use in the treatment of patients with degenerative and post-traumatic arthritis in the first metatarsal joint in the presence of good bone stock along with the following clinical conditions; hallux valgus or hallux limitus, hallux rigidus, and an unstable or painful metatarsal/phalangeal (MTP) joint. The device is a single use implant intended to be used with bone cement.

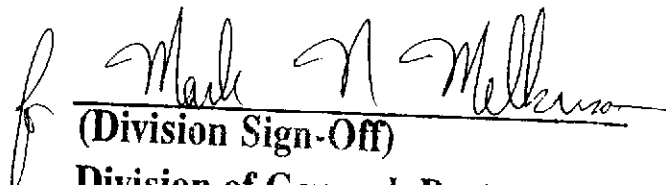
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes
(Per 21 CFR 801.109)

Over-The Counter Use No

(Optional Format 1-2-96)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K031859